



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/986,568	12/05/1997	JEAN-FRANCOIS BACH	040388/0110	5102

7590 03/18/2003

STEPHEN A BENT
FOLEY & LARDNER
3000 K STREET NW SUITE 500
PO BOX 25696
WASHINGTON, DC 200078696

EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 03/18/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

986,568

Applicant(s)

BACH et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 12/10/02
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-2, 4-7, 9-13, 16-18 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-2, 4-7, 9-13, 16-18 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1624

Claims 1-2, 4-7, 9-13, 16-18 are pending and under examination.

Claims 1, 6, 9-13 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant did not possess the genus of "anti-CD3 active compounds."

The rejection of record in paper 28 is maintained. Applicant traversed this as a 112, 2nd rather than a 112, 1st rejection. Therefore, though one in the art might "understand the meaning" of this term is not relevant. The "meaning" is merely a functional description and not a structural description that permits one to distinguish what compounds do or do not belong to the genes. That the previous examiner may have accepted the term is not considered relevant, because the issues that were presented to the BPAI were argued prior to the written Description Guidelines. Therefore, because of mechanistic differences in the diabetes found in mice and humans, it is considered that undue experimentation would be required to practice the claimed invention.

Claims 1, 2, 4-7, 9-13 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not enabled the treatment of established autoimmune disease in humans.

The rejection of record is maintained, since applicant's admitted in the Chatenoud reference that such therapy is only a possibility. Applicant has urged that mice have long been known by immunologists as "providing a standard model for immunological testing." However, the office does not consider it clear that the diabetes in NOD mice has the same mechanistic basis as human diabetes. For example, the diabetes in the animal model is predominantly found in females, whereas the diabetes in humans is found equally in both sexes. It is noted that applicant treated only female NOD mice in his examples (see page 4, lines 26-28).

Claims 1-2, 4-6, 9-13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatenoud et al (PNAS, 91, 123, 1994), for reasons of record.

Applicant has urged that the examiner's rejection is incorrect because the BPAI found that the Chatenoud et al. reference inherently anticipated the claimed invention and that the claims now before the examiner have been amended to overcome the BPAI'S decision. Upon review of the decision on appeal (paper 24), the present examiner notes that the position of inherency was based upon the interpretation of various words such as "transient" and "durable", and upon the fact that applicant's claimed steps were the same, irrespective of whether the treatment obtained was "transient" or "durable". Merely changing the claims from "mammal" to "human" treatment methods does not overcome what was found by the BPAI with respect to the above record. The change merely alters the basis of rejection from 102 to 103.

Applicant's urgings filed 12/10/02 have been considered but are unconvincing of patentability.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday 8 am - 5:30 pm. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-3973 for regular communications and (703) 308-4242 for After Final communications.

Application/Control Number: 08/986,568

Page 5

Art Unit: 1624

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Saunders/tgd
March 17, 2003

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644